If one order form is insufficient to include all items in an order, additional forms are used. The last line completed is noted on that form in the space provided. This number should correspond to the number of lines used. For example, if two lines are used on an order form to describe one item, the number of lines completed at the bottom is two.

- An item consists of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item is made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item, the form should show the name of the product ordered, the finished or bulk form of the product (e.g., 10-mg. tablet, 10-mg. concentration per fluid ounce or milliliter or U.S.P), the number of units or volume in each commercial or bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the product if not in pure form. The catalogue number of the product may be included at the discretion of the purchaser.

- The correct name and address of the supplier from whom the controlled substances are being ordered is entered on the form. Only one supplier may be listed on any one form.

- Each order form is signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to **21CFR 1305.05(c).** The name of the purchaser, if different from the individual signing the order form, is inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspection or to enforce any federal, state or local law regarding controlled substances.

Centralized Purchasing of Schedule II Drugs

When the ordering of schedule II drugs and the processing of the DEA Forms 222 is handled by Corporate Purchasing, the following steps are taken:

- Corporate Purchasing orders DEA Form 222's by contacting the appropriate DEA office or the DEA Registration Unit in Washington, D.C., or by completing a 222 Requisition Form.

  Note: All 222 Requisition Forms received by the divisions should be forwarded to Corporate Purchasing.

- Order Form Books are received at the division.
- The division logs the order form numbers onto the **DEA Narcotic Blank Log.**
- Division retains adequate supply of order forms for emergency purchases and customer return buybacks and forwards remainder to Corporate Purchasing, along with a copy of the **DEA Narcotic Blank Log.**

- Corporate Purchasing receives and stores order forms in a secure area. Corporate Purchasing contacts division if numbers are out of sequence or an order form is missing.
- Corporate Purchasing creates Schedule II purchase order and completes order form according to DEA regulations **(21 CFR 1305.06).**
- Copy 1 (brown) and Copy 2 (green) copies of order form are mailed to the vendor; Copy 3 (blue) is mailed to the division. Corporate Purchasing makes copy of the order form for purchasing records.

  Note: All three copies of voided order forms must be sent to the division.
- Corporate Purchasing adds order form numbers to purchase orders and transmits purchase order file to the division.
- Division receives Copy 3 (blue) copy of order form and records appropriate information onto **DEA Narcotic Blank Log**. Division contacts Corporate Purchasing if numbers are out of sequence or an order form is missing.

Power of Attorney

(21 CFR 1305.07)

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a **Power of Attorney (Form #2)** for each such individual. The **Power Of Attorney** is signed by the same person who signed or was authorized to sign, the most recent application for registration or re-registration and by the individual being authorized to obtain and execute order forms. The power of attorney is filed with the executed order forms of the purchaser, and retained for the same period as any order form bearing the signature of the attorney. The power of attorney should be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a **Notice Of Revocation (Form #3),** signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, or by whomever signed the most recent application for registration or re-registration, and filing it with the power of attorney being revoked.

Sales of Schedule I and II Substances

Procedure for Filling Order Forms

(21 CFR 1305.09)

- The purchaser submits copy 1 (brown) and copy 2 (green) of the order form to the supplier and retains copy 3 (blue) in his/her own files.

  Note: Order forms given by customers to contract drivers for eventual delivery to the distribution center must be in a sealed envelope. The driver should have no knowledge of the contents of the order form. ***Refer to DEA Correspondence 07-18-96.***

- The supplier fills the order, if possible and if the supplier desires to do so, and records on copies 1 (brown) and 2 (green)the number of commercial and bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days after its execution by the purchaser, except as noted below.

- The controlled substances are shipped to the purchaser at the location printed by the administration on the order form, except as noted below.

- The supplier retains copy 1(brown) of the order form for his/her own files and forwards copy 2 (green) to the special agent in charge of the DEA field office in the area in which the supplier is located. Copy 2 (green) is forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, copy 2 (green) is forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

- The purchaser records on copy 3 (blue) of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

  Note: Order forms submitted by registered procurement officers of the Armed Services Medical Procurement Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order forms, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

  Note: DEA Policy is that the wholesaler or a "direct proprietary agent" of the wholesaler must have the order form in hand before the product is released. The direct proprietary agent can be a sales representative, a depot supervisor or a driver (not common or contract).

Substitutions

It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution. **Refer to DEA Correspondence 6/29/92.**

Faxing Narcotic Order Forms

DEA, as a matter of policy, has stated that they will allow the faxing of order forms when it involves a direct transmission from the customer to the wholesaler; however, the order may not leave the distribution center until the original order form arrives at the distribution

center or is in the possession of a direct proprietary agent of the wholesaler. DEA may grant approval in emergency situations on a case-by-case basis for shipping the order before receiving the order form.

The DEA is also not opposed to having order forms faxed from depots to the wholesaler when the following conditions are met:

- The original order forms, when delivered to the depot, are in the possession of an employee of the wholesaler who is familiar with order form regulations.
- The order forms and a **DEA 222 Transmission Log (Form #5)** are faxed to the division and order form receipt is verified to the log.
- Narcotic orders are **not** released at the depot unless there is a corresponding order form.
- The regulatory requirements for the processing of DEA Form 222 are strictly adhered to.

This procedure **shall not be used unless** the depot operation is supervised by a Cardinal employee, the Cardinal employee faxes the order forms, and the Cardinal employee maintains possession of the original order forms until the order forms are exchanged for the controlled substances.

DEA **will not permit,** under any circumstances, the faxing of order forms from contract carrier crossdock locations by contract carrier employees. **Refer to DEA Correspondence 07-18-96 and 08-28-96.**

The faxing of 222s for customers serviced by contract carriers must be handled as follows:

FROM THE CROSSDOCK:

1. Contract delivery drivers deliver original 222s in sealed envelopes to contract carrier crossdock supervisor.

2. Crossdock supervisor delivers sealed envelopes containing 222s to Cardinal crossdock employee.

3. Cardinal crossdock employee removes 222s from envelopes and **completes DEA222 Transmission Log** (Form #5).

4. Cardinal employee faxes 222s to distribution center. **This should be done using one transmission and the DEA222 Transmission Log should be the last page of the fax.**

5. Fax is received in distribution center by Operations Manager or designee.

6. Operations Manager or designee verifies faxed 222s received with information on the DEA 222 Transmission Log. Faxed copies of 222s are checked for legibility and compliance and are processed according to DEA regulations.

    a) If any discrepancies exist that would require 222s to be re-faxed, Operations Manager or designee contacts Cardinal crossdock employee.

7. Cardinal crossdock employee places original 222s in a sealed envelope for delivery to the distribution center.

8. Operations Manager or designee delivers faxed 222s to the vault.

9. Vault clerk fills orders and files faxed 222s. Orders are held until original 222s arrive at the distribution center and are compared to the orders.

FROM THE CUSTOMER:

1. Customer faxes 222 directly to the distribution center.

2. Operations Manager or designee checks 222 for legibility and compliance and processes according to DEA regulations.

   a) If any discrepancies exist that would require 222 to be re-faxed, Operations Manager or designee contracts the customer.

3. Customer gives original 222 to contract delivery driver in a sealed envelope for delivery to distribution center.

4. Operations Manager or designee delivers faxed 222 to the vault.

5. Vault clerk fills order and files faxed 222. The order is held until the original 222 arrives at the distribution center and is compared to the order.

Preservation of Order Forms

(21 CFR 1305.13)

- The purchaser retains copy 3 (blue) of each filled order form. The purchaser also retains in his/her files all copies of each unaccepted or defective order form and any statements attached to them.

- The supplier retains copy 1 (brown) of each order form that has been filled.

- Order forms must be maintained separately from all other records of inspection for two years (as are all records of controlled substance transactions). If a purchaser has several registered locations, copy 3 (blue) of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to **(21 CFR 1305.06 (d))** must be kept at the registered location printed on the order form.

  Note: State record keeping requirements may be more than two years and records should be maintained accordingly.

Unaccepted and Defective Order Forms

(21 CFR 1305.11)

Federal regulations applicable to the handling of such order forms are as follows:

- No Order Form shall be filled if it:

  (1) Is not complete, legible, or properly prepared, executed, or endorsed; or

  (2) Shows any alteration, erasure, or change of any description.

- If an Order Form cannot be filled for any reason under this section, the supplier shall return Copies 1 (brown) and 2 (green) to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept the order; a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

- When received by the purchaser, Copies 1 (brown) and 2 (green) of the Order Form and the statement shall be attached to Copy 3 (blue) and retained in the files of the purchaser in accordance with **21 CFR 1305.13**. A defective Order Form may not be corrected; it must be replaced by a new Order Form in order for the order to be filled.

- Any information which is pre-printed on the order form may not be altered in any way.

Pursuant to these regulations, order forms should be returned to the customer under the following circumstances:

- The writing is illegible or it is otherwise impossible to identify a customer's registration number, items specified or quantities, or there is improper execution or endorsement.
- There are alterations, erasures, or changes resulting in questions regarding the identity of the customer, customer's registration number, items or quantities.
- Signatures are omitted.
- Sixty days have elapsed from the date of execution by the purchaser.
- The last line completed is greater than the last line specified.
- The number of line items is greater than the total number of items specified.
- Customer voids a line.

Federal order forms which identify the customer's registration number, items and quantities, and which are properly signed but are incomplete or have minor errors may be corrected to the following extent:

- The supplier's name, address, city, state, or zip code may be added when omitted by the customer.
- The supplier's address, city, state or zip code may be corrected.
- The date of the order may be added when omitted. Whenever possible, the postal date on the envelope should be used.

- It is permitted to add or change hydrochloride, sulfate, phosphate, ampules, tablets, etc. if the customer's order is correct in all respects except that it is specified in error; for example, specifies capsules and the product requested is properly designated and supplied in tablets.
- A letter or digit in the National Drug Code designation may be corrected if the controlled substance is described correctly, or the strength stated may be corrected if the quantity of controlled substance is not increased in any way.
- Order forms may be accepted when the customer has sent all three copies of the form to the supplier, but the customer's copy must be forwarded to him in advance of the shipping product.
- Order forms received by the supplier without interleaf carbon may be accepted, but the supplier must insert a replacement carbon between the forms before making any entries on the form.
- If a form is received which lists a package amount which is unavailable, a lesser amount may be shipped (e.g. order is for package size 100, if unavailable may ship package size 50), or if a form is received which lists a package amount which is unavailable, different package sizes not to exceed the original amount may be shipped (e.g. ordered 1 x 1000, may ship 10 x 100).
- Lesser number of line items ordered than line items specified, if the supplier crosses out the remaining lines before filling the form.
- Last line completed has been incorrectly noted. The order form should not be rejected when it is clear that this is due to misinterpretation, rather than an attempt to facilitate diversion.

A single item must be canceled for the following reasons, but the balance of the order may be shipped:

- If the number of packages, size of package, or strength has been altered by the person preparing the order form.
- If the item requested is discontinued or not listed, or is a non-controlled substance or is a controlled substance other than a Schedule I or II controlled substance.
- Strength is dittoed on the order form rather than designated.
- Strength is omitted (except trademark items when National Drug Code numer is listed).
- Size of package incorrectly stated (quantity may be reduced).
- Size of package omitted.
- When a multiple item order is properly prepared and complete in all other respects but a single item has a non-correctable defect, this item may be canceled in lieu of returning the order form to the customer.

Refer to DEA Correspondences 6/29/92, 12/16/92, 7/28/94, and 9/14/95 for regulatory interpretations.

Cancellation and Voiding of Order Forms

(21 CFR 1305.15)

- A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier indicates the cancellation on copies 1 (brown) and 2 (green) of the order form by drawing a line through the canceled items and printing "Canceled" in the space provided for number of items shipped.

- A supplier may void part or all of an order form by notifying the purchaser in writing of such voiding on an **Order Form Rejection Notification (Form #6).** The supplier should keep a copy of the order form and the notification. The supplier indicates the voiding in the manner prescribed for cancellation in paragraph (a) of this section.

- No cancellation or voiding permitted by this section affects in any way contract rights of either the purchaser of the supplier.

Narcotic Order Form Review

The DEA has established specific criteria for the acceptance of Narcotic Order Forms. To assure that the appropriate personnel receive continuous training with respect to these regulatory requirements, the previous day's Narcotic Order Forms must be reviewed for compliance with DEA regulations. Complete a **Narcotic Order Review Form (Form #7)** for any order forms that were processed in violation of DEA regulations. Discuss violations and the appropriate responsive action with personnel involved. File the Narcotic Order Review Form with a copy of the corresponding DEA Form 222.

Procedure for Endorsing Order Forms

(21 CFR 1305.10)

- An order form made out to any supplier who cannot fill all or part of the order within the time limitation set forth in 1305.09 may be endorsed to another supplier for filling. The endorsement is made only by the supplier to whom the order form was first made, states (in the space provided on the reverse sides of copies 1 (brown)and 2 (green) of the order form) the name and address of the second supplier, and is signed by the person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier fills the order if possible and if the supplier desires to do so, in accordance with **21 CFR 1305.09(b),(c) and (d)** including shipping all substances directly to the purchaser.

- Distribution made on endorsed forms is reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is

requested on the reporting form, the second supplier records the name, address and registration number of the first supplier.

Lost or Stolen Order Forms

(21 CFR 1305.12)

- If a purchaser ascertains that an unfilled order form has been lost, the purchaser should execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods ordered in the first order form were not received through loss of that order form. Copy 3 (blue) of the second order form and a copy of the statement are retained with copy 3 (bue) of the order form first executed. A copy of the statement is attached to copies 1 (brown) and 2 (green) of the second order form sent to the supplier. If the first order form subsequently is received by the supplier to whom it was directed, the supplier marks it as "Not accepted" and returns copies 1 (brown) and 2 (green) to the purchaser, who attaches it to copy 3 (blue) and the statement.
- Whenever any used or unused order forms are stolen or lost (besides in the course of transmission) by any purchaser or supplier, immediately upon discovery of the theft or loss, that person reports it to the local office of the Drug Enforcement Administration stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, the supplier should report the date or approximate date of receipt and the names and addresses of the purchasers. If an entire mailing envelope of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms it contained, the purchaser should report, in lieu of the numbers of the forms contained in the envelope, the date or approximate date the envelope was issued. If any unused order form reported lost or stolen subsequently is recovered or found, the Registration Unit should be notified immediately.

Return of Unused Order Forms

(21 CFR 1305.14)

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address shown on the registration), or is suspended or revoked (pursuant to **21 CFR 1301.45** or **1301.46** of this chapter), the purchaser (or his/her executor) should return all unused order forms for controlled substances listed in Schedules I and II for which the purchaser is registered to the nearest DEA office.

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METHAMPHETAMINE CONTROL ACT RECORDKEEPING AND REPORTING REQUIREMENTS (21 CFR 1310)

Pursuant to the Domestic Chemical Diversion and Control Act, DEA has regulated both RX and OTC single-entity ephedrine products since 1994. The Methamphetamine Control Act of 1996 extends these regulations and DEA control to the distribution of OTC combination ephedrine, pseudoephdrine and phenylpropanolamine products. A list of these products covered by the regulations is included as **Appendix E.**

The requirements which became effective October 3, 1997 are not the same as those for controlled substances. These products will not be scheduled, will not have to be kept in secure storage, and complete inventory accounting and ARCOS reporting requirements do not apply.

The MCA regulatory scheme, described in 21 CFR, Part 1310, has four basic components: registration; keeping records of ephedrine, pseudoephedrine and phenylpropanolamine transactions; reporting any unusual losses or excessive purchases to DEA, and taking steps to be sure the purchaser is legitimate.

Registration

Distributors who handle covered products are required to register as a chemical distributor with DEA, however DEA has exempted anyone with a valid DEA controlled substance registration from having to obtain the additional registration.

Your customers should have either a DEA controlled substance registration or a chemical registration.

Please note that there is a pseudoephedrine and phenylpropanolamine registration exemption for customers who meet the definition of a "retail distributor." Retail distributor is defined as a grocery store, drug store or other entity or person whose activities as a distributor of legal drug products containing listed chemicals are limited almost exclusively to sales for personal use (approximately 1200 dosage units), both in number and volume of sales, either directly to walk-in customers or in face to face transactions by direct sale.

The exemption process should be handled on a case by case basis. Customers not currently registered with DEA who believe they qualify for the exemption should be requested to provide written documentation to this effect. Once the documentation is received, the customer can be set up to purchase these items.

Note: A review of Cardinal's customer database has indicated that the vast majority of customers currently possess a valid DEA registration. Additionally, customers who do not possess such a registration are of a class that would not typically purchase these products.

Records

You must maintain readily retrievable records of each ephedrine, pseudoephedrine or phenylpropanolamine product transaction for 2 years. Normal business records shall be considered adequate, as long as they contain:

- the name and address of each party to the transaction
- the date of the transaction
- the name, quantity, and form of packaging of the ephedrine or pseudoephedrine product
- the method of transfer
- the type of identification used by the purchaser.

Reports

You must report to your local DEA office:

- Any unusual ephedrine, pseudoephedrine or phenylpropanolamine transaction -- extraordinary quantity, uncommon method of payment or delivery, or any other suspicious circumstances
- Any unusual or excessive loss of ephedrine, pseudoephedrine or phenylpropanolamine product. Pay particular attention to variances discovered during semi-annual inventories
- Any proposed transaction with a person DEA has requested in writing that you monitor (report **before** completing the sale).

Note: a transaction may not be completed with a person identified by DEA unless approved by DEA. Steps should be taken to prohibit sales to these persons.

Reports are to be made orally, whenever possible, to the local DEA office at the earliest opportunity and as much in advance of the sale as possible. A written report must then be filed within fifteen days of becoming aware of the above circumstances. Written reports must contain the same information as the required records, plus the telephone number of the other party, if possible, and a description of the circumstances leading you to make the report. Written reports should be made on the **MCA Transaction Report (Form #8).**

Identifying the Customer

The regulations require the wholesaler to "identify the other party" to the transaction. In general, an ongoing agreement with your customer, an account that you had for some time, and other such business relationships indicating you know your customer, should establish the kind of verification DEA is looking for. Credit applications and Dun and Bradstreet reports should be sufficient.

Compliance Guidelines

- Verify that your customers are registered to purchase these products or are exempt from the registration requirement.
- Maintain required records (normal business records are sufficient if they contain the required information).
- Generate and review monthly the MCA dosage limit report (Exhibit R). Submit these reports to DEA.
- Report to DEA any unusual or excessive loss or disappearance of any ephedrine, pseudoephedrine or phenylpropanolamine product. Pay particular attention to variances discovered during semi-annual inventories.
- Maintain a file consisting of any reports submitted to the DEA and the monthly Excessive Purchase Report.

Other Regulated Products

The requirements for ephedrine, pseudoephedrine and phenylpropanolamine also apply to other chemical products which wholesalers do not usually stock or stock and distribute in limited quantities. The recordkeeping and reporting requirements for these items, which are listed below, only apply when threshold limits set by the regulations are exceeded. A past review of sales history for the items that are stocked in certain Cardinal Distribution Centers indicated that typical distribution quantities do not come close to meeting these limits. However, division management should be aware of all regulated products in the event that DEA addresses this issue during an audit.

List I Chemicals:		
	Chemical	Threshold by base weight
1	Anthranilic acid and its salts	30 kilograms
2	Benzyl cyanide	1 kilogram
3	Ergonovine and its salts	10 grams
4	Ergotamine and its salts	20 grams
5	N-Acetylanthranilic acid and its salts	40 kilograms
6	Piperidine and its salts	500 grams
7	3, 4-Methylenedioxyphenyl-2-propanone	4 kilograms
8	Methylamine and its salts	1 kilogram
9	Ethylamine and its salts	1 kilogram
10	Propionic anhydride	1 gram
11	Isosafrole	4 kilograms
12	Safrole	4 kilograms
13	Piperonal	4 kilograms
14	Hydriotic acid (57%)	1.7 kilograms (or 1 liter by volume).
15	Benzaldehyde	4 kilograms
16	Nitroethane	2.5 kilograms

List II Chemicals:			
Imports and Exports			
	Chemical	Threshold by volume	Threshold by weight
(A)	Acetic anhydride	250 gallons	1,023 kilograms
(B)	Acetone	500 gallons	1,500 kilograms
(C)	Benzyl chloride	N/A	4 kilograms
(D)	Ethyl ether	500 gallons	1,364 kilograms
(E)	Potassium permanganate	N/A	500 kilograms
(F)	2-Butanone (MEK)	500 gallons	1,455 kilograms
(G)	Toluene	500 gallons	1,591 kilograms

Domestic Sales			
	Chemical	Threshold by volume	Threshold by weight
(A)	Acetic anhydride	250 gallons	1,023 kilograms
(B)	Acetone	50 gallons	150 kilograms
(C)	Benzyl chloride	N/A	1 kilograms
(D)	Ethyl ether	50 gallons	135.8 kilograms
(E)	Potassium permanganate	N/A	55 kilograms
(F)	2-Butanone (MEK)	50 gallons	145 kilograms
(G)	Toluene	50 gallons	159 kilograms

Note: The cumulative threshold is not applicable to domestic sales of Acetone, 2-Butanone (MEK), and Toluene.

	Chemical	Threshold by volume	Threshold by weight
(A)	Hydrochloric acid	50 gallons	.....
(1)	*Anydrous hydrochloric acid*	.....	*27 kilograms*
(B)	Sulfuric acid	50 gallons	.....

REQUIRED REPORTS TO DEA

Wholesalers are required to report regularly to DEA's ARCOS Unit all receipts and disposals of all Schedule I and II drugs and Schedule III narcotics. In addition, wholesalers are required to submit other reports to DEA under certain circumstances (e.g., drug thefts, drug destructions and suspicious orders).

ARCOS Reports

(21 CFR 1304.33)

Every wholesaler who handles controlled substances in Schedule I and II and/or narcotics in Schedule III must report to the ARCOS Unit, as follows:

When

Annual Inventory	To be taken on December 31
Initial Inventory	To be taken on the effective date that a substance becomes reportable
Transaction Reporting	Quarterly, or, with DEA permission, monthly

All reports are required to be submitted within 15 days after the end of the report period by certified or registered mail, return receipt requested.

- **ARCOS reports sent via commercial carrier such as Federal Express (FedEx), United Parcel Service (UPS) should be sent to:**

  DEA Headquarters
  Attn: ARCOS Unit
  2401 Jefferson-Davis Highway
  Alexandria, VA 22301

- **ARCOS reports sent via the U.S. Postal Service must use the following address:**

  Drug Enforcement Administration
  ARCOS Unit
  P.O. Box 27273
  Washington, D.C. 20038-7273

Refer to The ARCOS Reporting Manual (Appendix A) for additional information.

Optional ARCOS Reporting Modes

Registrants using punched card accounting machines or electronic data processing equipment should submit either card decks or magnetic tapes. Registrants without automated systems must use the Manual **ARCOS OCR Form - DEA Form 333 - (Form #9).**

Reporting ARCOS Data from Another Location

For authorization to report ARCOS data from other than a registered location, a central reporting identified must be obtained from the ARCOS unit at the above address.

DEA Order Forms

(21 CFR 1305.09 (d))

Copy 2 (green) of the order form shall be sent to the local DEA office at the close of the month during which the order was filled. If the order is filled by partial shipments, Copy 2 (green) shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

Drug Thefts/Losses

(21 CFR 1301.74(c))

The registrant notifies the DEA field office in that area of any theft or significant loss upon discovery of such theft or loss on **Report of Theft or Loss of Controlled Substances -DEA Form 106- (Form #10).** Reports must be submitted within seven (7) days of the incident. Reporting in-transit losses is the supplier's responsibility. Reporting responsibility for shipments for which you have a signed receipt lies with the customer.

The reporting of inventory variances on DEA form 106 must be carefully evaluated. The most recent DEA policy addressing this issue reads as follows: "DEA regulations require a registrant to maintain inventory records to track the flow of controlled substances but do not require the maintenance of perpetual inventories. If a firm elects to regularly track inventory balances and notes a theoretical discrepancy, the firm should make every effort to resolve it within a timely manner. If it is determined that an actual discrepancy is the result of a theft or significant loss of controlled drug product, then the nearest DEA field office must be notified immediately upon discovery and the theft or loss must be reported on a DEA Form 106." Variances which are the result of record keeping or order filling errors need not be reported.

Any ARCOS reportable items filed on **DEA Form 106** should also be submitted to ARCOS.

Note: Some state agencies require copies of all DEA Forms 106 filed with DEA.

Drug Destructions

(21 CFR 1307.21)

If a wholesaler wants to destroy certain controlled substances (e.g., damaged goods, returns, etc.), the wholesaler should notify the DEA special agent in charge on **Registrant Inventory of Drugs Surrendered - DEA Form 41 - (Form #11)** in triplicate. The special agent in charge will inform the wholesaler how the drug destruction will be handled. Where the wholesaler regularly disposes of controlled substances, the DEA special agent in charge can, upon request, authorize dispositions without prior approval provided that these dispositions are recorded fully and meet all conditions established by the special agent in charge. Destructions of reportable items must be submitted to ARCOS on **ARCOS OCR Form 333**.

> *Note: It is DEA's policy that if a state agency having jurisdiction over wholesalers has adopted disposal procedures for controlled substances, the wholesaler may follow these procedures in lieu of DEA requirements.*

Cardinal has a contract with Reverse Management Systems to handle our destruction of unsaleable merchandise. The product is sold to Reverse Management Systems who in turn destroys it and files **DEA Form 41**. **Refer to DEA Correspondence 8/12/94 for additional information.**

DEA Form 41 should also be used for documenting a liquid controlled substance loss when the container accidentally breaks. Any loss of an ARCOS reportable item must also be reported to ARCOS. The pieces of the broken bottle do not need to be retained as evidence of the accident. **Refer to DEA correspondence 11/17/97.**

Suspicious Orders

(21 CFR 1301.74(b))

Wholesalers are responsible for designing and operating a system that will disclose to the wholesaler suspicious orders. The wholesaler informs the DEA field office in that area of all suspicious orders. Suspicious orders include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency. DEA has no specific form for this.

Establishing Suspicious Order Criteria

Wholesalers should establish **written** criteria of what constitutes a suspicious order. DEA leaves it to the wholesaler to make this determination. The key for the wholesaler is to establish **reasonable** criteria based upon customer purchasing patterns and then to **adhere** to them in monitoring orders. Either a computerized or a manual system can be utilized depending upon the wholesaler's preference and capability.

Complying with 21 CFR 1301.74 (b) is a two-step process. First, each Cardinal Division submits to DEA on a monthly basis an Ingredient Limit Report (Exhibit M). This report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.

Second, on a daily basis cage and vault personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA should be notified, if possible, before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file along with a Regulatory Agency Contact Form (Form #1) noting any specific instructions from DEA.

In an effort to assist cage and vault personnel in identifying these orders, we have developed Dosage Limit Charts (Exhibit P). The products included on these charts are those commonly audited by DEA during their inspections of our facilities and those which have a high potential for diversion. The dosage limits were set by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items.

These charts should be posted in your cage and vault and the hospital and retail dosage limit quantities for particular items should be posted at the product locations.

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INTRODUCTION

Security is defined as the elements necessary to deter burglary or theft of controlled substances at a level of effectiveness that equals or exceeds federal regulations applicable to wholesaling. The elements include:

- Physical structures and barriers such as safes, vaults, cages, barricades, grilles, gates, fencing, locks and lighting;
- Electronic systems including burglary detection sensors and controls, emergency (holdup) signal devices, closed-circuit TV surveillance and recording equipment, access control systems, and communications devices; and
- Practices and procedures applicable to the installation, maintenance, inspection, testing and supervision of interrelated security devices and systems.

This section of the manual is provided to educate employees about DEA security requirements and to assist Division Management in evaluating compliance with these requirements.

In evaluating the overall effectiveness of a wholesaler's security against theft and diversion, DEA may consider, in addition to those security requirements previously discussed, any of the following factors:

- The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);
- The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);
- The quantity of controlled substances handled;
- The location of the premises and the relationship such location bears on security needs;
- The type of building construction comprising the facility and the general characteristics of the building or buildings;
- The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;
- The type of closures on vaults, safes, and secure enclosures;
- The adequacy of key control systems and/or combination lock control systems;
- The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;
- The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

- The adequacy of supervision over employees having access to manufacturing and storage areas;
- The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
- The availability of local police protection or of the registrant's or applicant's security personnel, and;
- The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

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